

ORDE “KNOW YOUR AGENCY” SERIES: PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Agency Site: <https://www.pcori.org/>

OVERVIEW

PCORI was created as part of the Patient Protection and Affordable Care Act and signed into law by President Obama in 2010. The agency was recently reauthorized by Congress for an additional 10 years. PCORI is charged with providing a better understanding of prevention, diagnosis, and treatment options for patients, their caregivers, health care providers, and other stakeholders. This charge is met through 1) research, 2) an emphasis on research methodology and 3) efforts to encourage other funding agencies to incorporate patient-centered research methods. PCORI is supported through the Patient Centered Outcomes Research Trust Fund, combining federal and fee-based revenue for agency operation.

Specific Interests

Patient-centered is not just in this agency’s name, it drives their every action. Patients and caregivers are involved in every step of the research process and PCORI has become an expert on proper engagement tactics, all with the goal of influencing healthcare for the betterment of patients. PCORI’s National Research Priorities are:

1. Assessment of Prevention, Diagnosis, and Treatment Options
2. Improving Healthcare Systems
3. Communication/Dissemination Research
4. Addressing Disparities
5. Accelerating Patient-Centered Outcomes Research and Methodological Research
6. Strategies for Improving Maternal Mortality*
7. Improving Health for Individuals with Intellectual and/or Developmental Disabilities*

**Note the last two priorities were added in the 2019 Reauthorization legislation (Executive Director’s Blog, 9/8/20).*

Approach

PCORI refers to their approach as “research done differently” (PCORI About Us Webpage), starting with establishment of strict methodology standards for

patient-centered outcomes research. Their Engagement Program involves patients, caregivers, healthcare industry leaders, healthcare advocates, and other stakeholders in all aspects of PCORI’s operation – actively contributing to the planning process and serving as key participants on research teams as well as the proposal review process.

AGENCY ORGANIZATION

PCORI is a 501(c)(1) corporation, not a federal agency. It is governed by a 21-member Board of Governors, drawn from academia, the health care industry, corporations outside of health care and non-profits, as well as the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality. PCORI’s Methodology Committee’s role is to identify best practice patient-centered research methods and to ensure these methods are employed in all research supported by PCORI. Committee members are experts in science, medicine, epidemiology, health care technology and the health care industry. Both the Board and the Committee are appointed by the US Comptroller General.

RESEARCH CONTRACTS PROGRAM

PCORI promotes their research contracts program through PCORI Funding Announcements (PFAs), characterized as Broad, Targeted, Improving Methods, and Implementation PFAs. Broad PFAs solicit investigator-initiated projects addressing one or more of PCORI’s National Research Priorities. Targeted PFAs focus on specific topics prioritized by patients and other health care stakeholders. Improving Methods PFAs are designed to answer questions about how best to conduct patient-centered outcomes research. Finally, Implementation PFAs allow previous patient-centered outcomes research results or effective shared decision-making approaches to be implemented in real-world situations. Project funding ranges from \$500,000 to several million dollars across 3-5 year project periods. Indirect costs are limited to 40%. Universities and colleges, private and public sector research organizations, non-profits, for-profits, hospitals, labs, manufacturers, and local/state/federal government agencies are eligible applicants.

Awards

As of September 2019, PCORI has provided nearly \$2.5 billion in research funding, representing 1000 projects since their inception.

Contact with Agency Program Staff:

PCORI encourages principal investigators (PIs) to contact program officers with questions and help in determining if research projects are applicable and responsive to PCORI needs via email or telephone. PCORI personnel are also available for online proposal submission questions.

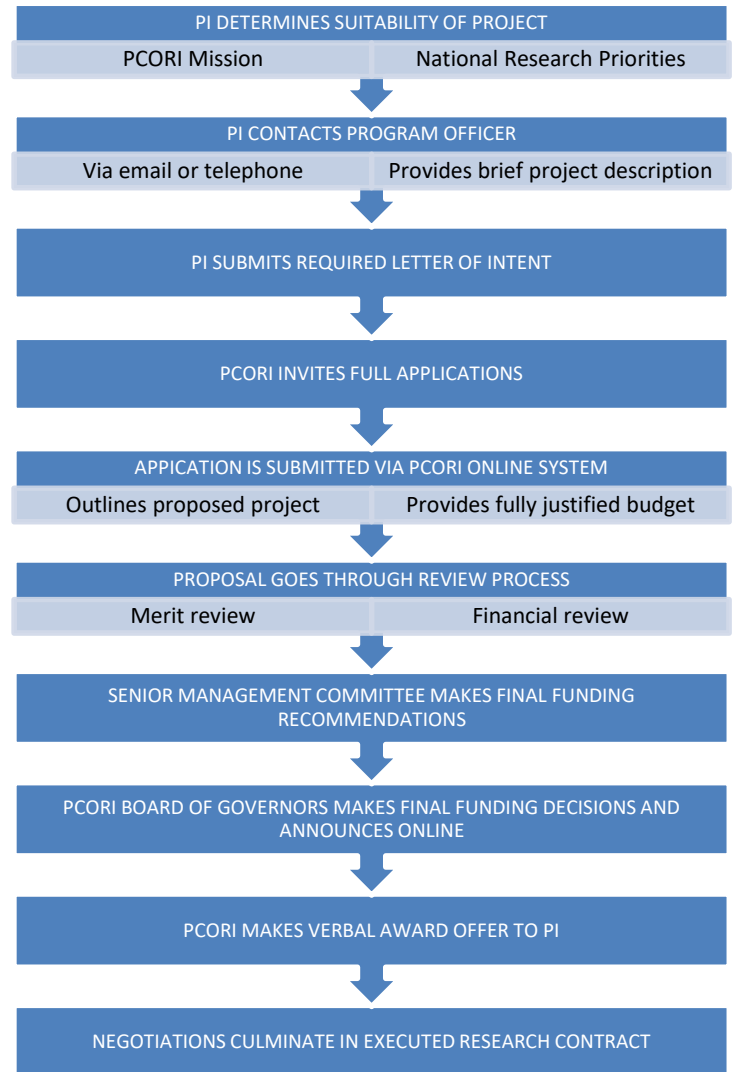
Typical PCORI Proposal Process:

- 1) PI determines suitability of proposed project to PCORI mission and National Research Priorities
- 2) PI contacts program officer for assistance and questions about application
- 3) PI submits required letter of intent (LOI); full applications are then invited by PCORI
- 4) The application is submitted through the PCORI online system
- 5) The application goes through merit review
- 6) Highest scoring applications go through financial review by procurement specialists
- 7) PCORI senior management committee reviews applications based on combined technical and cost scores for "best value"
- 8) PCORI Board of Governors makes final funding decisions
- 9) A verbal offer is made to the PI, followed by Best and Final negotiations
- 10) A research contract is executed

Application Review Process:

Scientists, patients, clinicians, patient advocates, caregivers, and other healthcare stakeholders are all actively involved in the PCORI review process. Each reviewer's score is equally weighted to ensure that all views are represented in final funding decisions. PCORI uses a 9-point scoring system with 9 being the lowest rank. The highest-ranking applications are then given cost scores by procurement specialists. A senior management committee makes final funding recommendations based on both merit and cost scores, and the PCORI Board of Governors approves awards. PCORI announces funding decisions via live Board of Governors' webinars, followed up by verbal notification, negotiation, and contract execution.

PCORI PROPOSAL & REVIEW PROCESS



What Happens Next?

Once research contracts are in place, PIs begin work on their projects. Those not selected for funding receive notice and can elect to go through a formal debriefing with agency personnel. PCORI has no resubmission limits so unfunded applicants should take advantage of the debriefing process and start planning their reworked applications in anticipation of the next round of funding.